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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,876	06/20/2005	Christine Power	SLII-P01-001	6247
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ROPE & GRAY LLP			DEBERRY, REGINA M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/510,876	<b>Applicant(s)</b> POWER ET AL.
	<b>Examiner</b> Regina M. DeBerry	<b>Art Unit</b> 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 January 2009.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 26-34 and 42-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 26-34 is/are rejected.
- 7) Claim(s) 42-51 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1668)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

### **Status of Application, Amendments and/or Claims**

The amendment and Applicant's arguments, filed 13 January 2009, have been entered in full. Claims 1-25 and 35-41 are canceled. Claims 26-34 and 42-51 are pending and under examination.

### **Withdrawn Objections And/Or Rejections**

The rejection to claims 26-34 and 42-51 under 35 U.S.C. 112, first paragraph, scope of enablement, as set forth at pages 4-7 of the previous Office Action (14 October 2008), is *withdrawn* in view of the amendment (13 January 2009).

The rejection to claims 26-34 and 42-51 under 35 U.S.C. 112, first paragraph, written description, as set forth at pages 7-8 of the previous Office Action (14 October 2008), is *withdrawn* in view of the amendment (13 January 2009).

The rejection to claims 27, 43 and 50 under 35 U.S.C. 112, second paragraph, as set forth at pages 8-9 of the previous Office Action (14 October 2008), is *withdrawn* in view of the amendment (13 January 2009).

### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d

1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-34 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32-66 of copending Application No. 10/966,845 in view of Franklin, Biochemical Pharmacology, Vol. 49, No. 3, pages 267-273 (1995). The basis for this rejection is set forth at pages 3-4 of the previous Office Action (14 October 2008).

Applicant requests that the Examiner hold this rejection in abeyance until this rejection is the sole remaining rejection in either the instant application or Application No. 10/966,845. Applicant notes that according to MPEP § 804 I.B. 1, "[i]f a 'provisional' nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer."

The instant rejection is maintained for reasons of record. The Examiner notes that copending application 10/966,845 is allowed but has not been issued.

## **NEW CLAIM REJECTIONS/OBJECTIONS**

### **Claim Objections**

Claims 26, 33 and 42-54 are objected to because of the following informalities:

"Disease" is misspelled in claim 26.

Claim 26 should recite "thereof" and "effective amount" instead of "therefor" and "effect amount"

Claim 33 should recite "..which occurs **at** one.." not "which occurs **as** one.."

Claim 43 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 42. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The Examiner rejected claim 43 under 112, second paragraph as being indefinite because of the recitation, "..produced by a cell genetically modified to produce said substance.." (previous Office Action; 14 October 2008; pages 8-9). The Examiner stated that it was unclear if the instant claim encompasses a substance being produced by a transgenic animal or produced recombinantly. The Examiner stated that if the latter case was correct, amending the claim to recite, "produced by an *isolated* cell genetically modified to produce said substance" would be remedial. Claim 42 recites, "the method of claim 26, wherein the substance is produced by an isolated cell". Claim 43 recites, "the method of claim 26, wherein the substance is produced by an isolated cell genetically modified to produce said substance". The instant claims appear to read on the same scope. If the claims

are not of similar scope, Applicant is asked to specifically point in the specification, the patentable distinction between claims 42 and 43. Applicant is cautioned that Inventions drawn to gene therapy (i.e. *in vivo* administering of nucleic acid, vectors, cell, etc.) were restricted out in the previous Office Action (Election/Restriction 31 July 2007). Applicant elected claims drawn to administering polypeptides (Group I) in the previous Office Action (07 November 2007).

Claims 42-51 are objected to for depending from a rejected claim.

Lastly, the Examiner suggests amending claim 26 to recite "a method for treating or inhibiting progression or inhibiting symptoms.." and adding an additional claim to recite, "the method of claim 26 wherein progression and symptoms are inhibited". The claims in copending application 10/966,845 have been amended to recite this language. It is recommended that the related applications recite the same language.

### **Conclusion**

Claims 26-34 are rejected.

Claims 42-51 are objected to.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/  
Primary Examiner, Art Unit 1647

/R. M. D./  
Examiner, Art Unit 1647  
4/25/09